**Part 1: Overview Information**

<table>
<thead>
<tr>
<th>Participating Organization(s)</th>
<th>Prostate Cancer Canada</th>
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</thead>
<tbody>
<tr>
<td>Funding Opportunity Title</td>
<td>Special Project in Non-Metastatic Castrate Resistant Prostate Cancer</td>
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</table>
| Description                  | Prostate Cancer Canada (PCC) invites applications for investigator-initiated Special Projects in non-metastatic castrate resistant prostate cancer (NM-CRPC). This request for applications (RFA) solicits proposals on groups interested in combining various real world data sources (i.e. detailed chart review at prostate cancer centres with health administrative databases) to obtain high quality epidemiological data, outcomes and costs among the population of prostate cancer patients in at least two provinces in Canada that together represent greater than 50% of the population.

The key objectives of this RFA are:

- to obtain prevalence, incidence and survival probability estimates of prostate cancer, stratified by age and year of diagnosis from provincial cancer registries;
- to identify pathways leading to and factors associated with the target condition non-metastatic castrate resistant prostate cancer (NM-CRPC);
- to estimate annual incidence and prevalence of NM-CRPC, stratified probability of developing NM-CRPC and transition probabilities that characterize the prognosis from NM-CRPC to metastasis and end-of-life;
- to estimate health care resource use and costs for health states in the recurrent disease model.

It is expected that a multidisciplinary approach will be required, including representative(s) from large academic cancer centres and at least one team member should have access to a major health records databases. Each application may consist of independent investigators based in multiple institutions. **PCC will only consider projects that are completely focused on prostate cancer.**
Important Dates

<table>
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<tr>
<th>Important Dates</th>
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<tbody>
<tr>
<td>Program Launch Date</td>
<td>December 14, 2015</td>
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<tr>
<td>Registration Deadline</td>
<td>February 3, 2016</td>
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<tr>
<td>Application Deadline</td>
<td>February 17, 2016</td>
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<tr>
<td>Peer Review</td>
<td>March 2016</td>
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<tr>
<td>Anticipated Award Notification Date</td>
<td>By March 31, 2016</td>
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<tr>
<td>Earliest Start Date</td>
<td>April 1, 2016</td>
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Part 2: Full Announcement

Section I. Funding Opportunity Description

Background
Prostate cancer is the most commonly diagnosed cancer among men, with an estimated 24,000 new cases being reported every year leading to 4,100 annual deaths from the disease, according to the 2015 Canadian Cancer Statistics. Patients diagnosed at early stages (i.e. localized or regional disease) have excellent survival, with overall five-year relative survival approaching 100%. However, for patients diagnosed with metastatic disease, prognosis is poor and five-year survival is estimated at only 28%. Treatment for metastatic prostate cancer includes androgen deprivation therapy or cytotoxic chemotherapy. The goal of therapy is to slow tumor growth, prolong survival and reduce symptoms secondary to metastatic disease. As new therapies emerge for treating locoregional, non-metastatic castrate resistant prostate cancer (NM-CRPC) and distant disease, it is important to understand the economic and disease burden of these different stages of disease in routine clinical practice and factors that could potentially be used to identify patients with high risk of metastasis.

Description
The focus of the proposed project should be on combining various real world data sources (i.e. detailed chart review at prostate cancer centres with health administrative databases) to obtain high quality epidemiological data, outcomes and costs among the population of prostate cancer patient in at least two provinces in Canada.

It is expected that a multidisciplinary approach will be required.

Objectives
The key objectives of this RFA are:

• to obtain prevalence, incidence and survival probability estimates of prostate cancer, stratified by age and year of diagnosis from provincial cancer registries;
• to identify pathways leading to and factors associated with the target condition NM-CRPC;
• to estimate annual incidence and prevalence of NM-CRPC, stratified probability of developing NM-CRPC and transition probabilities that characterize the prognosis from NM-CRPC to metastasis and end-of-life;
• to estimate health care resource use and costs for health states in the recurrent disease model.

Additional objectives of the program are:

• to support multidisciplinary groups of prostate cancer researchers;
• to support high quality research;
• to support the translation of research findings into improvements in the health of Canadians and the Canadian cancer care system.
Section II. Award Information

<table>
<thead>
<tr>
<th><strong>Funding Instrument</strong></th>
<th>Grant</th>
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<tbody>
<tr>
<td><strong>Application Types Allowed</strong></td>
<td>New</td>
</tr>
<tr>
<td><strong>Funds Available and Anticipated Number of Awards</strong></td>
<td>The total amount available for this funding opportunity is $450,000 over 2 years to fund 1 project.</td>
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<tr>
<td><strong>Award Budget</strong></td>
<td>An applicant may request a project period of up to 2 years at a budget of up to $450,000 total (direct costs).</td>
</tr>
<tr>
<td><strong>Award Project Period</strong></td>
<td>The maximum period is 2 years.</td>
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*The amount available for this program is subject to funds raised. Should funding levels decrease, PCC reserves the right to reduce, defer or suspend financial contributions to grants received as a result of this funding opportunity.

**This award anticipates a contract between the institution and PCC. Due to tight timelines, applicants may be asked to review a contract before the grant has been awarded, so that the agreement may be in place by April 1, 2016.*

Section III. Eligibility Information

Eligibility to Apply

The **Principal Investigator** is an independent investigator who will:

- be responsible for the direction of the proposed activities; and
- assume the administrative and financial oversight for the entire award; and
- assume the financial responsibility for his/her own portion of the award at his/her own institution; and,
- receive all related correspondence from PCC.

An **independent investigator** is an individual who:

- has an academic or research appointment which:
  - must commence by the effective date of funding; and
  - allows the individual to pursue the proposed research project, to engage in independent research activities for the entire duration of the funding, to supervise trainees, and to publish the research results; and
  - obliges the individual to conform to institutional regulations concerning the conduct of research, the supervision of trainees, and the employment conditions of staff paid with PCC funding.
- will assume financial responsibility for his/her portion of the award at his/her own institution and will be responsible for reporting this information back to the Program Director as well as to PCC.

A **Co-Principal Investigator** or a **Co-Investigator** is an independent investigator at an eligible Canadian institution and is part of the team contributing to the grant.
**Number of Applications**  
Applicants may only submit one application.

**Section IV. Guidelines and Review Process**

**General PCC Guidelines**  
PCC policies and guidelines as outlined on the PCC website will apply to the applications submitted and awards made in response to this RFA. PCC reserves the right to amend the review process at any time. Any changes that are made to the process will not adversely affect the rigor and equity of the process. Every effort will be made to inform applicants of changes in a timely manner.

**Evaluation**  
An expert review panel will be established to evaluate proposals submitted to this RFA. The review panel will make recommendations to PCC as to which proposals should be funded based on the following criteria:

1. Overall objective and extent of innovation of the program of research  
2. Significance/relevance of the research  
3. Feasibility of the clinical implementation of the project  
4. Leadership capabilities and track record of the Principal Investigator  
5. Capacity of the research team to carry out the program of research proposed  
6. Institutional support for the program  
7. How the proposal complements and builds upon existing projects in this area

**Allowable Costs**  
The following expenditures will be considered eligible for funding received through this funding opportunity:

- Research operating costs for the proposed research program, which must be distinct in its objectives from those for which group members currently receive funding;
- Purchase of small equipment and maintenance contracts for common services and shared infrastructure essential to the proposed research program (maximum budget to be no more than 5% of the total annual budget per grant year);
- Costs of data collection, database and maintenance of information holdings directly related to the proposed research program;
- Costs of regional, national and international networking activities, including collaboration, planning, and knowledge exchange activities, directly related to the proposed research program.
- Salaries of research assistants, technicians, program coordinator and other personnel who will enhance the collaborative research productivity of the program team;
- Stipends paid to trainees (e.g., undergraduate, graduate students, postdoctoral fellows) shall be in accordance with institutional policies, up to a maximum of $21,000 per annum for graduate students and $50,000 per annum for postdoctoral fellows.

**Non-Allowable Costs**  
The following expenditures are NOT eligible for funding received through this funding opportunity:
• Indirect costs associated with the conduct of research (including, but are not limited to, heating, lighting, ethics review, CTA application, and intellectual property and commercialization activities).

Conditions of Funding
Successful applicants funded through this funding opportunity must fully comply with the following conditions:
• Acknowledgment of Janssen Inc. (“Janssen”) and PCC’s support in all publications and presentations that result from the funded research. In addition, PCC would ask that PCC staff is notified prior to publication of a research paper.
• The PI will be required to submit to PCC annual written progress reports that include a list of all publications resulting in whole or in part from this grant, as well as lay summaries for each publication.
• Financial statements must be submitted to PCC annually no later than 45 days after the end of each grant year by the PI receiving funds from PCC.
• The PI will be required to submit to PCC a final written report with a final financial statement.
• The final report will be shared with Janssen on a confidential basis, and solely for Janssen’s internal use.
• Ownership and the assignment of the rights to any Intellectual Property will be in accordance with the Intellectual Property Policy of the Host Institution. At this time, PCC will not take or be assigned ownership to any Intellectual Property

Performance Indicators
Performance indicators will be developed in order to evaluate the success of this grant.

Section V. Submission Information
Please read all instructions before applying.
• The application process for this funding opportunity is comprised of two steps: Step 1 - Registration and Step 2 - Full Application.
• To complete your registration, please follow the instructions found below.
• Please ensure that your registration is complete (includes all required sections) and is submitted online on time to PCC.

Phase 1 – Registration Requirements
Your registration must be submitted online by February 3, 2016. A link to the online application will be provided at www.prostatecancer.ca Registration Submission
1. Participant info:
   • Principal Investigator (PI)
   • Co-Principal Investigators (Co-PI)
   • Co-Investigators (Co-I)
   Note: Collaborators may be identified at the full application stage.
The Principal Investigator will provide the single point of contact between PCC and the research team.

Each named participant in these categories must qualify as an independent investigator:

- An individual who has an academic or research appointment which:
  - Must commence by the effective day of funding; and
  - Allows the individual to pursue the proposed research project, to engage in independent research activities for the entire duration of the funding, to supervise trainees, and to publish the research results; and
  - Obliges the individual to conform to institutional regulations concerning the conduct of research, the supervision of trainees and the employment conditions for staff paid with PCC funding
- Will assume financial responsibility for his/her portion of the award at his/her own institution and will be responsible for reporting this information back to PCC.

Attachment: (to be attached to the Full Application): Abbreviated CVs for PI, each Co-PI and Co-I:
Include the following information:
- Training and education
- Degrees
- Positions and honours
- Relevant publications (past 5 years)
- Research Support, ongoing and completed (past 5 years)

2. **Host Institution** (one only)
   Name the Host Institution (HI) for the Principal Investigator, name and title of the HI signing authority

3. **Area of Research**

4. **Project Title**

5. **Keywords** (5-10)

6. **Reviewer Recommendations** (5-10)
   For each, list (international recommendations preferred):
   - Name
   - Institution
   - Contact info including e-mail address
   - Area of expertise
   - Related Team Grant component/project /aim

7. **Reviewer exclusions** (optional): For each, list:
   - Name
   - Institution
   - Reason for exclusion
   Note that assigned reviewers will have access to this information.
After the REGISTRATION deadline and before the FULL APPLICATION deadline, changes can only include removal of participants. Changes must be requested by email submission of specifics to: joanne.reynolds@prostatecancer.ca.

Phase 2 – Full Application Submission Requirements

8. Financial Officer (from the Host Institution)

9. Certificates required: Identify institution(s) and relevant project(s) for each type of certificate required:
   • Biohazard/Biosafety
   • Animal Care
   • Ethics
   • Stem Cells

10. List of collaborators: A Collaborator can be: an independent investigator (inside or outside Canada), a graduate student, a postdoctoral fellow, a research associate or technical support staff who contributes to the project. List all collaborators by name and institution.
    Attachment: Letters of Collaboration

11. Scientific Abstract (250 words): Provide a summary of the proposed research, indicating specific aims, methodology of the proposed research, intended outcomes and potential significance to prostate cancer.

12. Lay Summary (250 words): Using non-scientific language, provide an overview of the proposed research project. Include a short summary of aims of the projects, a brief overview of the knowledge in this area, a description of the proposed research and a statement of how the proposal meets the criteria for the Janssen Translation Acceleration Grants (TAG) competition.

13. Detailed Proposal (total 5,000 words)
   Note: Each application may be composed of one single project or distinct projects that are tightly linked within a program.
   For each project detail the goals and specific aims, significance of the problem and how it is innovative. Describe the strategy, methodology and analyses to be used along with potential problems, alternative strategies, expected outcomes and impact that the results will have on that area of research.
   The feasibility of the clinical implementation of the project must also be described in detail.

    Attachment: Related tables/figures can be attached; maximum 5 pages.
    References

14. Detailed Budget with Justification:
   There is no yearly maximum, however budget request must average $225,000/year over the term of the grant for up to 2 years; e.g. 2 years=$450,000/ Overall total and year by year totals must match detailed budget figures. Show consolidated budget for entire program year by year:
   o Salaries
• Stipends to trainees
• Small equipment (maximum 5% of total budget)
• Research materials and supplies
• Services
• Data collection, database management
• Regional, national and international networking activities
• Other expenses

• Provide full justification for all budget elements

15. Current and Pending Funding
Using the categories: 1) Active Grants and 2) Pending Grants, provide one consolidated list that includes information for the Principal Investigator and all additional Co-Investigators using the following format:

List each grant only once, clearly indicating all of the applicants that are affiliated with the team grant. The following format is to be used:

• Title of Grant
• Source
• Grant #
• Dollars Awarded
• Dates of Approved Project (start/end)
• Name of PI
• List of Co-investigators
• The major goals of this project
• % of Overlap with current application

Attachment: Abstracts must be attached for each grant or pending grant, ensuring that the title of the project is clearly indicated on the abstract.

Attachments:

1. CVs for each Principal Investigator, Co-Principal Investigator and Co-investigator. Include:
   • Training and education
   • Degrees
   • Positions and honours
   • Relevant publications (past 5 years)
   • Research Support, ongoing and completed (past 5 years)

2. Letters of Collaboration
Attach one document that contains all Letters of Collaboration.

3. Tables/Figures related to the proposal
   • Please include Table or diagram showing all proposed projects and shared resources and their relationship within the proposed program.

4. Current and Pending Funding Abstracts
Abstracts must be attached for each grant or pending grant, ensuring that the title of the project is clearly indicated on the abstract.

5. References related to the proposal
6. **Reprints/Abstracts**: maximum 5 relevant to the application

7. **Signature Page** – signed by Principal Investigator, all Co-Principal Investigators, Co-Investigators, Host Institution Financial Officer, Host Institution Signing Authority (Dean/Head of Department of the Principal Investigator)

This opportunity is funded by Janssen Inc. through a Research Fund Sponsorship to PCC, defined as financial support for an organizational/institutional research project fund. Research award recipients are at the sole discretion of Prostate Cancer Canada.

**Contact Information**
For questions relating to this RFA please contact:

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jenna.fong@prostatecancer.ca

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joanne.reynolds@prostatecancer.ca

For more information on this funding opportunity, visit prostatecancer.ca.